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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,527	04/15/2004	Bum-Joon Kim	5823.0260-00	7151

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

SITTON, JEHANNE SOUAYA

ART UNIT	PAPER NUMBER
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1634

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<div style="border: 1px solid black; width: 150px; height: 20px; margin: 0 auto;"></div> <p style="text-align: center;">Office Action Summary</p>	Application No. 10/824,527	Applicant(s) KIM ET AL.	
	Examiner Jehanne S. Sitton	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4, 12 and 14 is/are allowed.
- 6) ☒ Claim(s) 1-3, 10, and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 5/15/2007 has been entered.

2. Currently, claims 1-10 and 12-14 are pending in the instant application. Claims 5-9 are withdrawn from consideration as being drawn to a non elected invention. Claim 14 is considered generic and linking to the inventions in claims 3, 4, and 13. As claim 14 is allowable, the inventions in claims 3 and 13 have been rejoined and the restriction requirement between the SEQ ID NOS is hereby withdrawn. Claims 1-4, 10, and 12-14 are currently under examination. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow, where applicable. This action is Non-FINAL.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. The objection to the specification is withdrawn, as set forth in the advisory action mailed 4/9/2007, section 2.

Claim Rejections - 35 USC § 101

5. Claim 3 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim recites a 'gene fragment', however the term is not limited to less than a full coding sequence but also encompasses genomic sequences as well as RNA which could exist in nature. The claims therefore do not distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non naturally occurring differences between the claimed products and naturally occurring ones. In the absence of the hand of man, the naturally occurring products are considered non statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor.

Claim Rejections - 35 USC § 112

Indefinite

6. Claims 1-3, 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The lack of the use of commas (,) in claims 1, 2, and 10, is confusing because it is not clear if the claims are directed to a primer which consists of the recited sequence, or to a primer which amplifies the recited sequence. Originally, the examiner had assumed the former was the

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case, however if this is so, it is not clear why claim 10 was amended to its present form as it would be identical in scope with claim 2, that is, both claims directed to a primer consisting of SEQ ID NO: 2. The only difference in the recitation of claim 2 and claim 10 is the specificity language in claim 10, which is absent from claim 2. However, if the former is the case, the language carries no additional weight and the claims are still structurally directed to a primer which consists of SEQ ID NO: 2. As such, claims 2 and 10 would be substantial duplicates and subject to objection. If the former is the case, as appears to be so given the guidance in the specification, it is suggested that claim 10 be canceled, and claims 1 and 2 be amended to simply recite "A primer consisting of the sequence of SEQ ID NO: 1 [2, respectively]", as the additional language regarding amplification adds no structural limitations to the claims.

Claim 3 is indefinite in the recitation of "a groEL2 gene fragment or fragment thereof". The double use of the term "fragment" makes it unclear if the claim encompasses a nucleic acid which comprises one of the indicated SEQ ID NOS: or a fragment of one of the indicated SEQ ID NOS, or both.

The use of the term "chosen from" in claims 3 and 13 does not conform with Markush language. Claim 3 was amended from proper Markush format "selected from the group consisting of" to the instantly recited claim, while claim 13 was written from original claim 4, which was also amended from proper Markush format. The use of the term "chosen from" is indefinite because it is unclear if the sequences are "chosen" from the group of SEQ ID NO: 3 to 42, or 44-61, respectively, or also include sequences from within the recited SEQ ID NOS.

7. Applicant is advised that should claim 2 be found allowable, claim 10 would be subject to possible objection under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims

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in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). See possible claim interpretation in section 6 above.

Written Description

8. Claims 3, 10 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 3 and 13 are directed to nucleic acids "derived from" *Streptomyces* species or a potato scab microorganism, respectively. The claims recite "comprising language" with regard to the indicated SEQ ID NOS, and therefore encompass sequences which comprise one of the indicated SEQ ID NOS, as well as sequences "derived" therefrom. Accordingly, the claim encompasses a genus of nucleic acids which can contain any number of sequences on either side of the indicated SEQ ID NOS. The recitation of "derived from" appears to indicate that the sequences could also be changed in some way so as to be considered "derived" from an original sequence, and thus the genus also encompasses sequences which can be changed from the indicated SEQ ID NOS. The partial gene sequences of the recited SEQ ID NOS is not representative of the genus of sequences encompassed by the claims which could be "derived" from potato scab microorganisms or *Streptomyces* species because it is not clear which

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sequences could be changed and still be considered "derived" from the indicated microorganisms.

Although the specification teaches that 648 bp fragments were amplified by SEQ ID NOS 1 and 2 for *Streptomyces scabiei*, *Streptomyces acidiscabies*, *Streptomyces turgidiscabies*, *Streptomyces bottropensis*, *Streptomyces disastatochromogens*, and *Streptomyces neyagawanensis*, and further teaches the sequence of smaller 420 bp fragments from within these amplicons, the genus of fragments encompasses those derived from any potato scab source, including other species of *Streptomyces*, such as *Streptomyces europoiscabies*, *Streptomyces stelliscabiei* and *Streptomyces reticuliscabiei* (isolated from netted scab lesions), as well as other organisms such as *Spongospora subterranea subterranea* and *Spongospora subterranea nasturtii* (see Merz, et al; European Journal of Plant Pathology, vol. 11, page 371-379, 2005), which have not been taught or described by the specification. The species disclosed are not representative of the large genus encompassed by the claims because the skilled artisan would not be able to envision the structure of these sequences simply based on the disclosure of the primers of SEQ ID NOS 1 and 2, or the sequences of partial amplicons from *Streptomyces*. As noted by the specification, the 420 bp fragments are variable, which allows for distinction between them, however without a written description of the actual sequences encompassed by the claims, one of skill in the art would not be able to predict their structure.

Claim 10 has been amended such that it appears to encompass any primer which specifically amplifies SEQ ID NO: 2. That is, the claim encompasses any primer which will amplify SEQ ID NO: 2 and no other sequence. However, the specification provides no guidance

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as to which sequences from within SEQ ID NO: 2 would specifically amplify any groEL2 gene or SEQ ID NO: 2, but no other sequence.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of nucleic acids comprising a nucleic acid sequence selected from the group consisting of SEQ ID NOS: 3-61, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993), and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it

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obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

Claim Rejections - 35 USC § 102

9. Claims 1-3, 10 and 13 are rejected under 35 USC 102(b) as being anticipated by Brennan (US Patent 5,474,796).

Brennan teaches an array comprising all possible 10 mer nucleic acid sequences (see cols 9-10). Claim 3 encompasses a genus of fragments of the recited SEQ ID NOS. Claims 1, 2, and 10 appear to encompass sequences from within SEQ ID NO: 1 or 2. Claims 3 and 13 are also directed to fragments "chosen from" the indicated SEQ ID NOS, which appears to encompass sequences from within the indicated SEQ ID NOS. Accordingly, the fragments taught by Brennan anticipate the fragments encompassed by the claims.

10. Claims 3 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession number M76658 (1993).

The specification does not define the recitation of "derived from". Accordingly, the claims have been broadly interpreted to encompass sequences from the indicated microorganisms which can be changed from the SEQ ID NOS indicated. Genbank Accession number M76658 is a sequence from *Streptomyces albus*. Accordingly, this sequence anticipates

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the claims as it is "derived" from a *Streptomyces* species as well as a potato scab pathogenic microorganism.

Conclusion

11. Claims 4, 12, and 14 are allowed. Claims 1 and 2 would be allowable if rewritten as follows:

"A primer, which amplifies the groEL2 gene fragment of at least one *Streptomyces* species, consisting of the nucleotide sequence of SEQ ID NO: 1 [2]." (with commas).

Or

"A primer consisting of the nucleotide sequence of SEQ ID NO: 1 [2]" (without commas).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jehanne Sitton
Primary Examiner
Art Unit 1634

7/31/07